Microvascular lesions in the brain: a new perspective on cognitive impairment in type 2 diabetes

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Primary Objective: 1) To compare the prevalence en number of microbleeds at 7T between older people with and without DM2, and to relate the lesions to cognitive performanceSecondary Objective(s): 1) To characterize cerebral microinfarcts at 7T and...

Ethical review	Not approved
Status	Will not start
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON33315

Source
ToetsingOnline

Brief title
Cerebral microvascular lesions in type 2 diabetes

Condition

- Diabetic complications
- Encephalopathies
- Vascular haemorrhagic disorders

Synonym
type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: brain imaging, cognition, microvascular lesions, Type 2 diabetes

Outcome measures

Primary outcome

The prevalence and total number of microinfarcts and microbleeds at 7T in

relation to DM2 status and cognition.

Secondary outcome

Microvascular lesion load will be related to cognition, conventional MR markers

(atrophy, white matter hyperintensities), diabetes status and vascular risk

factors.

Study description

Background summary

Type 2 diabetes (DM2) is associated with cognitive decrements and an increased risk of dementia. Further insight in the natural history and etiology of these decrements is required to optimize treatment. We aim to identify novel brain imaging correlates of impaired cognition in DM2, which may serve as a surrogate outcome measure in future intervention studies.
Neuropathological studies identify microvascular lesions, i.e. microinfarcts and microbleeds, as important correlates of impaired cognition in older individuals, but these lesions go largely undetected on conventional MR imaging. The introduction of high field strength clinical MR scanners now enables the detection of these lesions in vivo. Pilot studies have shown that the prevalence of microbleeds at 7T is 10 times higher than detected with 3T MR.

Our hypotheses are that
- microvascular lesions, detected at 7T, are more common in patients with DM2 than in aged matched controls
- a higher lesion load is associated with impaired cognition

Study objective

Primary Objective:
1) To compare the prevalence en number of microbleeds at 7T between older people with and without DM2, and to relate the lesions to cognitive performance

Secondary Objective(s):
1) To characterize cerebral microinfarcts at 7T and to relate these lesions to DM2 and cognition
2) To relate the microvascular lesions at 7T to conventional imaging markers of DM2
3) To relate the microvascular lesions at 7T to diabetes status and to diabetes associated vascular risk factors

Study design

This is an observational cross-sectional population-based study

Study burden and risks

Approximately 600 eligible individuals will undergo a short telephone interview including a cognitive screening test (10 min). Based on the interview 140 individuals will be visited at home for a detailed neuropsychological assessment (1 hour). From this group, 112 will be selected for a visit to the UMC Utrecht. The visit includes a medical examination (30 min) in which blood is drawn (3x5ml, 1x10ml), a 1.5Tesla and 7Tesla MRI scan of 30 minutes each. There are no health risks associated with the procedures and techniques used.

Contacts

Public
Universitair Medisch Centrum Utrecht

heidelberglaan 100, postbus 85500
3508 GA Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

heidelberglaan 100, postbus 85500
3508 GA Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age between 65 and 80 years diabetes patients: diagnosed with diabetes for more than 1 year

Exclusion criteria

Dementia - TIA or non-invalidating stroke in the past 2 years or any invalidating stroke. - Other neurological diseases, unrelated to DM2, that are likely to affect cognition, including a history of brain trauma requiring hospitalisation - Known with or history of psychiatric disorders requiring hospitalisation or >12 months medication use (e.g. schizophrenia , Major depression (DSM IV)) - Contra-indication for 7 Tesla MR imaging (as established by the department)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	140
Type:	Anticipated

Ethics review

Not approved

Date:	15-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL29297.041.09